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Boehringer Ingelheim Pharma GmbH & Co.
KG, Boehringer Ingelheim International
GmbH, and Boehringer Ingelheim
Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,
BOEHRINGER INGELHEIM
INTERNATIONAL GMBH, and
BOEHRINGER INGELHEIM
PHARMA GMBH & CO. KG,

Plaintiffs,

v.

AUROBINDO PHARMA USA INC., et al.,

Defendants.

Civil Action No. 17-7887 (MAS)(LHG)
Civil Action No. 17-7923 (MAS)(LHG)
Civil Action No. 17-8399 (MAS)(LHG)
Civil Action No. 17-8819 (MAS)(LHG)
Civil Action No. 17-8825 (MAS)(LHG)
Civil Action No. 17-11510 (MAS)(LHG)
Civil Action No. 18-3244 (MAS)(LHG)
Civil Action No. 18-11350 (MAS)(LHG)
(consolidated)

(Filed Electronically)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, “Boehringer”) and Defendant Sandoz Inc. (“Sandoz”) have resolved the above action for good cause and valuable consideration recognized by Boehringer and Sandoz. Now the parties, by

their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and injunction in this action as follows:

IT IS, this 4th day of August, 2021

HEREBY ORDERED, ADJUDGED AND DECREED that:

1. For purposes of this action only, this Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over Boehringer and Sandoz.

2. As used in this Consent Judgment and Order of Permanent Injunction, (i) the term “the Asserted Patents” means U.S. Patent Nos. RE 43,431 and 8,426,586, which Sandoz agrees are valid and enforceable, (ii) the term “Sandoz’s ANDA Products” shall mean the products described in Abbreviated New Drug Application No. 210703, including afatinib dimaleate tablets as a generic version of Gilotrif[®], as existing on the Effective Date, and as amended or supplemented from time to time in the ordinary course of business, and (iii) the term “Affiliate” shall mean any entity controlling, controlled by, or under common control with a Party, but only as long as such control continues, where “control” means: (i) the ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for or appoint a majority of the board of directors or other governing body of such entity; or (ii) the power to directly or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever; provided, however, that with respect to Sandoz, “Affiliate” shall mean Eon Labs Inc., Fougera Inc., and Oriel Therapeutics Inc.

3. Except as specifically authorized by Boehringer, Sandoz, including any of its successors and assigns, is enjoined from making, having made, using, selling, offering to sell, importing, or distributing Sandoz’s ANDA Products, on its own part or through any Affiliate, officer, agent, servant, employee, or attorney, or through any person in concert or coordination

with Sandoz or its Affiliates, through and until the last expiration of an Asserted Patent, including any patent term extension and/or patent term adjustment, and the period of any pediatric exclusivity associated with an Asserted Patent. If Boehringer becomes entitled to any other regulatory exclusivities that are not referenced herein, Boehringer may apply to the Court for modification of the injunction to incorporate such specified exclusivity.

4. The Parties agree that, in the event of a violation of the terms of this Consent Judgment and Order of Permanent Injunction, jurisdiction and venue for an action to enforce performance under this Consent Judgment and Order of Permanent Injunction, including for a preliminary injunction against the breaching conduct, exists in this District Court, and the Parties hereby waive any and all defenses based on personal jurisdiction and venue.

5. Nothing in this Consent Judgment and Order of Permanent Injunction prohibits Sandoz or its Affiliates from maintaining a Paragraph IV Certification to the Asserted Patents in ANDA No. 210703 solely for the purposes of receiving or maintaining final approval of Sandoz's ANDA Products or prohibits FDA from granting final approval to ANDA No. 210703.

6. This Court retains jurisdiction to enforce or supervise performance under this Consent Judgment and Order of Permanent Injunction.

7. The Complaint and all remaining claims, counterclaims, or affirmative defenses in Civil Action No. 17-8825 (MAS)(LHG) are dismissed without prejudice and without costs, disbursements, or attorney fees to any party.

IT IS SO STIPULATED on this 26th day of July, 2021:

By:

s/ Charles M. Lizza

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SO ORDERED:

This 4th day of August, 2021

By:

s/ Eric I. Abraham

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HONORABLE MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE